(d) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and Facsimile (480) 767–1042 or *http://www.ncpdp.org*.

(1) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, IBR approved for § 170.205.

(2) SCRIPT Standard, Implementation Guide, Version 10.6, October, 2008, (Approval date for ANSI: November 12, 2008), IBR approved for § 170.205.

(3) [Reserved]

(e) Regenstrief Institute, Inc., LOINC® c/o Medical Informatics The Regenstrief Institute, Inc 410 West 10th Street, Suite 2000 Indianapolis, IN 46202–3012; Telephone (317) 423–5558 or *http://loinc.org/*.

(1) Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, June 15, 2009, IBR approved for § 170.207.

(2) [Reserved]

(f) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; Telephone (301) 594–5983 or *http://www.nlm.nih.gov/*.

(1) International Health Terminology Standards Development Organization Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), International Release, July 2009, IBR approved for § 170.207.

(2) [Reserved]

(g) Centers for Disease Control and Prevention, National Centers for Immunization and Respiratory Diseases Immunization Information System Support Branch—Informatics 1600 Clifton Road Mailstop: E–62 Atlanta, GA 30333.

(1) HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009, IBR approved for § 170.207.

(2) Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2, June 2006, IBR approved for § 170.205.

(3) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for § 170.205.

(4) [Reserved]

(h) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; Telephone (410) 786–3000

(1) CMS PQRI 2009 Registry XML Specifications, IBR approved for § 170.205.

(2) 2009 Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry, Version 3.0, December 8, 2008 IBR approved for § 170.205.

(i) National Institute of Standards and Technology, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930, *http://csrc.nist.gov/groups/STM/cmvp/standards.html*.

(1) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, January 27, 2010, IBR approved for § 170.210.

(2) [Reserved]

(j) American National Standards Institute, Health Information Technology Standards Panel (HITSP) Secretariat, 25 West 43rd Street—Fourth Floor, New York, NY 10036, *http://www.hitsp.org*

(1) HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component, HITSP/C32, July 8, 2009, Version 2.5, IBR approved for § 170.205.

[75 FR 44649, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010]

Subpart C—Certification Criteria for Health Information Technology

SOURCE: 75 FR 44651, July 28, 2010, unless otherwise noted.

§ 170.300 Applicability.

(a) The certification criteria adopted in this subpart apply to the testing and certification of Complete EHRs and EHR Modules.

(b) When a certification criterion refers to two or more standards as alternatives, use of at least one of the alternative standards will be considered compliant.

(c) Complete EHRs and EHR Modules are not required to be compliant with certification criteria that are designated as optional.

§ 170.302 General certification criteria for Complete EHRs or EHR Modules.

The Secretary adopts the following general certification criteria for Complete EHRs or EHR Modules. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically, unless designated as optional, and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Drug-drug, drug-allergy interaction checks—(1) Notifications.* Automatically and electronically generate and indicate in real-time, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE).

(2) Adjustments. Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.

(b) *Drug-formulary checks.* Enable a user to electronically check if drugs are in a formulary or preferred drug list.

(c) *Maintain up-to-date problem list.* Enable a user to electronically record, modify, and retrieve a patient's problem list for longitudinal care in accordance with:

(1) The standard specified in §170.207(a)(1); or

(2) At a minimum, the version of the standard specified in §170.207(a)(2).

(d) *Maintain active medication list.* Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care.

(e) *Maintain active medication allergy list.* Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care.

(f) *Record and chart vital signs—(1) Vital signs.* Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, height, weight, and blood pressure.

(2) Calculate body mass index. Automatically calculate and display body mass index (BMI) based on a patient's height and weight.

(3) Plot and display growth charts. Plot and electronically display, upon request, growth charts for patients 2–20 years old.

(g) *Smoking status.* Enable a user to electronically record, modify, and retrieve the smoking status of a patient. Smoking status types must include: current every day smoker; current some day smoker; former smoker; never smoker; smoker, current status unknown; and unknown if ever smoked.

(h) *Incorporate laboratory test results—(1) Receive results.* Electronically receive clinical laboratory test results in a structured format and display such results in human readable format.

(2) Display test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(3) Incorporate results. Electronically attribute, associate, or link a laboratory test result to a laboratory order or patient record.

(i) *Generate patient lists.* Enable a user to electronically select, sort, retrieve, and generate lists of patients according to, at a minimum, the data elements included in:

(1) Problem list;

(2) Medication list;

(3) Demographics; and

(4) Laboratory test results.

(j) *Medication reconciliation.* Enable a user to electronically compare two or more medication lists.

(k) *Submission to immunization registries.* Electronically record, modify, retrieve, and submit immunization information in accordance with:

(1) The standard (and applicable implementation specifications) specified in §170.205(e)(1) or §170.205(e)(2); and

(2) At a minimum, the version of the standard specified in §170.207(e).

(l) *Public health surveillance.* Electronically record, modify, retrieve, and submit syndrome-based public health surveillance information in accordance with the standard specified in §170.205(d)(1) or §170.205(d)(2).

(m) *Patient-specific education resources.* Enable a user to electronically identify and provide patient-specific education resources according to, at a minimum, the data elements included in the patient's: problem list; medication list; and laboratory test results; as well as provide such resources to the patient.

(n) *Automated measure calculation.* For each meaningful use objective with a percentage-based measure, electronically record the numerator and denominator and generate a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

(o) *Access control.* Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information.

(p) *Emergency access.* Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency.

(q) *Automatic log-off.* Terminate an electronic session after a predetermined time of inactivity.

(r) *Audit log. (1)—Record actions.* Record actions related to electronic health information in accordance with the standard specified in §170.210(b).

(2) Generate audit log. Enable a user to generate an audit log for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at §170.210(b).

(s) *Integrity.* (1) Create a message digest in accordance with the standard specified in §170.210(c).

(2) Verify in accordance with the standard specified in §170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

(3) *Detection.* Detect the alteration of audit logs.

(t) *Authentication.* Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.

(u) *General encryption.* Encrypt and decrypt electronic health information in accordance with the standard specified in §170.210(a)(1), unless the Secretary determines that the use of such algorithm would pose a significant security risk for Certified EHR Technology.

(v) *Encryption when exchanging electronic health information.* Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in §170.210(a)(2).

(w) *Optional. Accounting of disclosures.* Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in §170.210(d).

[75 FR 44651, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010]

§170.304 Specific certification criteria for Complete EHRs or EHR Modules designed for an ambulatory setting.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules designed to be used in an ambulatory setting. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Computerized provider order entry.* Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types:

(1) Medications;

(2) Laboratory; and

(3) Radiology/imaging.

(b) *Electronic prescribing.* Enable a user to electronically generate and transmit prescriptions and prescription-related information in accordance with:

(1) The standard specified in §170.205(b)(1) or §170.205(b)(2); and

(2) The standard specified in §170.207(d).

(c) *Record demographics.* Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, and date of birth. Enable race and ethnicity to be recorded in accordance with the standard specified at §170.207(f).

(d) *Patient reminders.* Enable a user to electronically generate a patient reminder list for preventive or follow-up

care according to patient preferences based on, at a minimum, the data elements included in:

(1) Problem list;

(2) Medication list;

(3) Medication allergy list;

(4) Demographics; and

(5) Laboratory test results.

(e) *Clinical decision support—(1) Implement rules.* Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.

(2) Notifications. Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

(f) *Electronic copy of health information.* Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in:

(1) Human readable format; and

(2) On electronic media or through some other electronic means in accordance with:

(i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems.* The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);

(B) *Laboratory test results.* At a minimum, the version of the standard specified in §170.207(c); and

(C) *Medications.* The standard specified in §170.207(d).

(g) *Timely access.* Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, and medication allergy list.

(h) *Clinical summaries.* Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list. If the clinical summary is provided electronically it must be:

(1) Provided in human readable format; and

(2) Provided on electronic media or through some other electronic means in accordance with:

(i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems.* The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);

(B) *Laboratory test results.* At a minimum, the version of the standard specified in §170.207(c); and

(C) *Medications.* The standard specified in §170.207(d).

(i) *Exchange clinical information and patient summary record—(1) Electronically receive and display.* Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list in accordance with the standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format.

(2) Electronically transmit. Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in accordance with:

(i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems.* The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);

(B) *Laboratory test results.* At a minimum, the version of the standard specified in §170.207(c); and

(C) *Medications.* The standard specified in §170.207(d).

(j) *Calculate and submit clinical quality measures—(1) Calculate* (i) Electronically calculate all of the core clinical measures specified by CMS for eligible professionals.

(ii) Electronically calculate, at a minimum, three clinical quality measures specified by CMS for eligible professionals, in addition to those clinical quality measures specified in paragraph (1)(i).

(2) Submission. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in §170.205(f).

§ 170.306 Specific certification criteria for Complete EHRs or EHR Modules designed for an inpatient setting.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules designed to be used in an inpatient setting. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Computerized provider order entry.* Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types:

(1) Medications;

(2) Laboratory; and

(3) Radiology/imaging.

(b) *Record demographics.* Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, date of birth, and date and preliminary cause of death in the event of mortality. Enable race and ethnicity to be recorded in accordance with the standard specified at §170.207(f).

(c) *Clinical decision support—(1) Implement rules.* Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.

(2) Notifications. Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

(d) *Electronic copy of health information.* (1) Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures:

(i) In human readable format; and

(ii) On electronic media or through some other electronic means in accordance with:

(A) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and

(B) For the following data elements the applicable standard must be used:

(1) Problems. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);

(2) Procedures. The standard specified in §170.207(b)(1) or §170.207(b)(2);

(3) Laboratory test results. At a minimum, the version of the standard specified in §170.207(c); and

(4) Medications. The standard specified in §170.207(d).

(2) Enable a user to create an electronic copy of a patient's discharge summary in human readable format and on electronic media or through some other electronic means.

(e) *Electronic copy of discharge instructions.* Enable a user to create an electronic copy of the discharge instructions for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means.

(f) *Exchange clinical information and patient summary record—(1) Electronically receive and display.* Electronically receive and display a patient's summary record from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures in accordance with the standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format.

(2) Electronically transmit. Enable a user to electronically transmit a patient's summary record to other providers and organizations including, at a minimum, diagnostic results, problem list, medication list, medication allergy list, and procedures in accordance with:

(i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems.* The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);

(B) *Procedures.* The standard specified in §170.207(b)(1) or §170.207(b)(2);

(C) *Laboratory test results.* At a minimum, the version of the standard specified in §170.207(c); and

(D) *Medications.* The standard specified in §170.207(d).

(g) *Reportable lab results.* Electronically record, modify, retrieve, and submit reportable clinical lab results in accordance with the standard (and applicable implementation specifications) specified in §170.205(c) and, at a minimum, the version of the standard specified in §170.207(c).

(h) *Advance directives.* Enable a user to electronically record whether a patient has an advance directive.

(i) *Calculate and submit clinical quality measures—(1) Calculate.* Electronically calculate all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals.

(2) Submission. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in §170.205(f).

Subpart D—Temporary Certification Program for HIT

SOURCE: 75 FR 36203, June 24, 2010, unless otherwise noted.

§170.400 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act, and sets forth the rules and procedures related to the temporary certification program for health information technology administered by the National Coordinator for Health Information Technology.

§170.401 Applicability.

This subpart establishes the processes that applicants for ONC–ATCB status must follow to be granted ONC–ATCB status by the National Coordinator, the processes the National Coordinator will follow when assessing applicants and granting ONC–ATCB status, the requirements that ONC–ATCBs must follow to remain in good standing, and the requirements of ONC–ATCBs for testing and certifying Complete EHRs and/or EHR Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part.

§170.402 Definitions.

For the purposes of this subpart:

Applicant means a single organization or a consortium of organizations that seeks to become an ONC–ATCB by requesting and subsequently submitting an application for ONC–ATCB status to the National Coordinator.

Deployment site means the physical location where a Complete EHR or EHR Module resides or is being or has been implemented.

Development site means the physical location where a Complete EHR or EHR Module was developed.

ONC–ATCB or ONC–Authorized Testing and Certification Body means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the testing and certification of Complete EHRs and/or EHR Modules under the temporary certification program.

Remote testing and certification means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC–ATCB to be physically present at the development or deployment site to conduct testing and certification.

§170.405 Correspondence.

(a) Correspondence and communication with the National Coordinator shall be conducted by e-mail, unless otherwise necessary. The official date of receipt of any e-mail between the